K083681

JAN 16 2009

510 (K) Summary

Submitter:

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Manufacturer:

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Device Name:

Proprietary Name Bioland Blood Pressure Monitor Model 2001, Model 2003, Model 2004, Model 2005, model 3000, Model 3001 and Model 3002
Common/Usual Name· Non-invasive Blood Pressure Measurement System
Device Name Non-invasive Blood-pressure Measurement System
Product Code DXN
Classification Class II

Predicate Device:

A & D LifeSource UA-704 Digital Blood Pressure Monitor (K032499),
A & D LifeSource UB-328 Digital Blood Pressure Monitor (K040229)
A & D Medical UA-767BT Digital Blood Pressure Monitor (k040371)

Product Code DXN
Manufacturer: A & D Engineering, Inc.
Establishment Number: 2082313
Owner/Operator Number: 8031633

Description and Intended Use:

Bioland Blood Pressure Monitor Model 2001, Model 2003, Model 2004, Model 2005, model 3000, Model 3001 and Model 3002, are Sphygmomanometers with Electronic Manometer intended to be used for the indirect (non-invasive) measurement of diastolic, systolic blood pressure and pulse rate for adults only.

Technological Characteristics:

Bioland Blood Pressure Monitor Model 2001 and Model 2004 respectively use an inflation cuff wrapped around the upper arm The cuff is inflated by a manual air pump

Bioland Blood Pressure Monitor Model 2003 and Model 2005 respectively use an inflation cuff wrapped around the upper arm. The cuff is inflated by an electrical air pump

Bioland Blood Pressure Monitor Model 3000, Model 3001 and Model 3002, respectively uses inflation cuffs wrapped around the wrists. The cuff is inflated automatically by an electrical air pump

The systolic, diastolic blood pressures and heart beats are transmitted via air pressure in the inflated cuff to transducer for the determination with oscillometric method. The cuff integrated with bladder is inflated by air pump The deflation rate is controlled and released by a preset mechanical valve at a constant rate beginning at the pressure peak during the measurement. The measurement results including diastolic, systolic pressures and heart pulse rate are displayed on the LCD

Device Tests

Bioland Blood Pressure Monitor Model 2001, Model 2003, Model 2004, Model 2005, MODEL 3000, Model 3001 and Model3002 meet ANSI/AAMI SP-10 standard and FDA guidance "Non-invasive Blood Pressure (NIBP) Monitor Guidance" Please refer to the table below for the list of AAMI SP-10 tests Bioland Blood Pressure Monitor Model 2001, Model 2003, Model 2004, Model 2005, Model 3000, Model 3001 and Model 3002 are clinically tested The applicant devices use the identical software codes and pressure detection related hardware as the predicate device to determine systolic, diastolic, and pulse rate Bioland Blood Pressure Monitor Model 2001, Model 2003, Model 2004, Model 2005, Model 3000, Model 3001 and Model 3002 comply with the standard EN 60601-1 1990, and EN 60601-1-2/2001, see Attachment 4, Electrical Safety Test Report and Attachment 5 & 6, EMC Test Report

SP10 Standard test result

SP-10 Section #	Title	Model 2001/2004	Model 2003/2005	Model 3000/3001/3002
		Test Results & Comments		
4.1 1	General	Conformed	Conformed	Conformed
1 1.2.1	Device labeling	Conformed	Conformed	Conformed
4 1 2.2	Outer container	Conformed	Conformed	Conformed
4.1 3	Information manual	Conformed	Conformed	Conformed
4.1 4 1	Component replacement	Conformed	Conformed	Conformed
4 1 4.2	Power system labeling	Conformed	Conformed	Conformed
4 1.4.3	Labeling for battery-powered devices	Conformed	Conformed	Conformed
4.2 1	Storage conditions	Conformed	Conformed	Conformed
4 2 2	Operating conditions	Conformed	Conformed	Conformed
4 2 3	Vibration and shock	Conformed	Conformed	Conformed
4.2 4 1	Voltage range	Conformed	Conformed	Conformed
4 2 4 2	Life	Conformed	Conformed	Conformed
4.3 1 1	Maximum cuff pressure	Conformed	Conformed	Conformed
4 3 1 2	Cuff deflation	Conformed	Conformed	Conformed
4 3 2	Electrical safety	Conformed	Conformed	Conformed
4 3 3	Conductive components	Conformed	Conformed	Conformed
4 4 1	Pressure indicator accuracy	Conformed	Conformed	Conformed
4 4 2	Overall system efficacy	Conformed	Conformed	Conformed
4 4 2.1	Auscultatory method as the reference standard	Conformed	Conformed	Conformed
4 4 2 2	Intra-aeterial method as the reference standard	Not applicable	Not applicable	Not applicable

4.4.3	Battery-powered devices	Conformed	Conformed	Conformed
4 5	Requirements for devices with manual Conform-ed inflation systems	Conformed	Conformed	Conformed

Clinical tests on blood pressure on patients using Bioland Blood Pressure Monitor Model 2001, Model 2003, Model 2004, Model 2005, Model 3000, Model 3001 and Model 3002 comparing to normal mercury-type sphygmomanometers were conducted in Feng Gang Overseas Chinese Hospital. The differences of measuring results between the electric Blood Pressure Monitor and normal mercury sphygmomanometers are briefly listed in the following table:

Item/Diff	Within+/-3mmHg	Within+/-5mmHg	Within+/-8mmHg
Model 2001/2003	78/87(89 7%)	84/87(96.6%)	87/87(100%)
Model 2004/2005	79/87(90.8%)	84/87(96.6%)	87/87(100%)
Model 3000/3001/3002	79/87(90 8%)	82/87(94 3%)	87/87(100%)

The accuracy of test result found acceptable

There was no any injury occurred during clinical test

Substantial Equivalency

All tests, including standards conformance and clinical, show the subject Devices Bioland Blood Pressure Monitor Model 2001, Model 2003, Model 2004, Model 2005, Model 3000, Model 3001 and Model 3002 are substantial equivalent to the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2009

Bioland Technology Ltd
c/o Mr Morten Simon Christensen
Underwriters Laboratories, Inc
455 E Trimble Road
San Jose, California 95131-1230

Re K083681
Trade/Device Name Bioland Blood Pressure Monitors Model 2001, Model 2003, Model 2004, Model 2005, Model 3000, Model 3001 and Model 3002
Regulation Number 21 CFR 870 1130
Regulation Name 'Non-Invasive Blood Pressure Measurement System
Regulatory Class Class II
Product Codes DXN
Dated January 5, 2008
Received January 12, 2008

Dear Mr Christensen

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index html

Sincerely yours,

Bram D Zuckerman, M D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name Bioland Blood Pressure Monitor Model 2001, Model 2003, Model 2004, Model 2005, model 3000, Model 3001 and Model 3002

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Prescription Use _____ **AND/OR** **Over-The-Counter Use** _X_

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTTNUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 1/16/09

Division of Cardiovascular Devices

510(k) Number K083681